Remarks

Applicants hereby elect group II, claims 24-30 and claim 41; without prejudice to file

divisionals on the non-elected groups.

Applicant has amended claim 1 to specify that the binding polymer has a molecular

weight of about 7,000 to about 100,000. Support for this amendment may be found at page 5,

line 25. Support for new claim 42 may be found at page 5, lines 1-10.

Examiner has rejected claims 24-36 and 41 as anticipated by or obvious in view of

Thrakrar (US 6,337,040). Thrakrar neither discloses nor suggests binding polymers comprising

2-hydroxyethyl methacrylate and any specific molecular weight. Clearly, the claims as amended

are novel in view of Thrakrar.

The claims as amended are also patentable in view of Thrakrar. Attached herewith is a

Declaration of Douglas Vanderlaan showing that polyHEMA having a molecular weight greater

than the range recited in the present claims is not soluble in the solvents disclosed and used in

the Examples in Thrakrar. Thrakrar is silent as to the molecular weight of the binding polymer.

Clearly, the claims are patentable in view of Thrakrar.

Withdrawal of the rejections and allowance of the claims as amended is respectfully

requested.

Respectfully submitted,

Reg. No. 33,967

Johnson & Johnson P.O. Box 1222

New Brunswick, NJ 08933

(904) 443-3074

Dated: July 16, 2004

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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants

: Frank Molock, et al.

Serial No.

: 10/027,579

Filed

: December 20, 2001

Title:

COLORANTS FOR USE IN TINTED CONTACT LENSES AND

METHODS FOR THEIR PRODUCTION

Art Unit

: 1732

Examiner

: Mathieu Vargot

Honorable Commissioner of Patents Alexandria, VA 22313

## **DECLARATION UNDER 37 CFR 1.132**

- I, Douglas Vanderlaan, PhD, declare as follows:
- 1.1 I am currently a Senior Scientist for Johnson & Johnson Vision Care, Inc. I received a Bachelor of Science in Chemistry from Calvin College, in 1979, and a Doctorate in Organic Chemistry from the Florida State University in 1984. I was a Research Fellow in the field of Organic Chemistry at the University of Michigan from 1984-1985. I was a Research Chemist at SWS Silicones from 1985-1986 and Senior Chemist at Reichhold Chemicals from 1986-1989. I have been a scientist for Johnson & Johnson Vision Care, Inc since 1989. In my tenure with Johnson & Johnson Vision Care, Inc. I have been engaged in research and study of materials for contact lenses
- 1.2 I reviewed the Examples of US 6,337,040 ("US `040") and tried to dissolve poly(2-hydroxyethylmethacrylate) (polyHEMA) in the solvents used in the Examples of US `040. No molecular weight was specified in US `040 for the binding polymers. The only molecular weight listed for polyHEMA in the 2000-2001 Aldrich Catalog was 300,000. A copy of page 1375 from the 2000-2001 Aldrich Catalog showing the polyHEMA entry is attached hereto.

- 1.3 I combined 2.0 g of poly(2-hydroxyethylmethacrylate) (300,000 M<sub>V</sub>, from Aldrich Chemicals) with 8.0 g 1-butanol and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.
- 1.4 I combined 3.0 g of poly(2-hydroxyethylmethacrylate) (300,000 M<sub>V</sub>, from Aldrich Chemicals) with 3.5 g 1-methoxy-2-propylacetate and 3.5 g cyclohexanone and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.
- 1.5 I combined 3.5 g of poly(2-hydroxyethylmethacrylate) (300,000 M<sub>V</sub>, from Aldrich Chemicals) with 3.25 g cyclohexanone and 3.25 g methyl ethyl ketone and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.
- 1.6 I combined 1.5 g of poly(2-hydroxyethylmethacrylate) (300,000 M<sub>V</sub>, from Aldrich Chemicals) with 8.5 g butoxy ethyl acetate and mixed for 3 hours at room temperature. The polymer showed no signs of dissolving and did not appear to be swelling.
- 1.7 None of the solvents used in the Examples of US `040 dissolved poly(HEMA) having a 300,000. Clearly US `040 did not appreciate the importance of molecular weight for binding polymers comprising poly(HEMA).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereof.

Inventor's Full Name

Douglas Vanderlaan, PhD

Signature

July 16, 2004

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		<b>s</b> .			•	\$
(ide) alcohol,		- : 15.90 43.00	44,570-3	Poly(3-hexyithiophene-2,5-diyl), regioregular [104934-50-1] mp 238° For the characterization and solid-state properties of this polymer, see <i>J. Am. Chem.</i> Soc. 1994, 117, 233.	1g	229.35
ddo) alaabat	مر	4=		Solid. Greater than 98.5% head-to-tail regiospecific conformation. Average M <sub>w</sub> ca. 87,000		7111
tide) alcohol, 1 <sub>2</sub> (OCH <sub>2</sub> CH <sub>2</sub> ) <sub>2</sub> OPO <sub>3</sub> H <sub>2</sub>	5mL 25mL	15.90 43.00		Product of Rieke® Metals, Inc.		. 1.54
•	•	, 10.00	51,082-3 ©	Poly(3-hexylthlophene-2,5-dlyl), regiorandom [104934-50-1] For solid state properties see J. Am. Chem. Soc. 1994, 117, 233		229.35
ide) monoalkylamide I8° d 1.700		15.90	1	Red solid. Conducting polymer. 1:1 (head-to-head):(head-to-tail) linkages of	et e	HERE S.
φ α 1.700	25g	43.00		regioisomers Product of Rieke® Metals, Inc. Poly(A-hydroxybenzoic acid-co-ethylene terephthalate) [125300-07-4]		
:lde)	5mL 25mL	15.90 43.00	49,709-6	Poly(4-hydroxybenzoic acid-co-ethylene terephthalate) [125300-07-4]	100g	20.00
:ide) monocarboxylic	5mL	15.90	43.234-2	Poly(4-hydroxybenzoic acid- <i>co</i> -6-hydroxy-2-naphthoic acid) [ <i>70679-92-4</i> ]	100g	21.10
3000 d 1.770 Fp none	- 25mL	43.00		, (-OC <sub>6</sub> H <sub>4</sub> CO-) <sub>x</sub> (-OC <sub>10</sub> H <sub>6</sub> CO-) <sub>y</sub> mp 280° d 1.500 Liquid crystal random thermoplastic copolymer. Average M <sub>w</sub> >20,000. Reinforced with	500g	<del>-</del> 70.20
.*			36 350-2	ca. 15% glass fiber  Poly(3-hydroxybutyric acid), natural origin [26063-00-3] [-COCH <sub>2</sub> CH(CH <sub>3</sub> )O-] <sub>n</sub>	10g	41.10
<sub>2</sub> C(CH <sub>2</sub> ) <sub>4</sub> CO-] <sub>n</sub>	250g	19.30	00,000	R&S 1(2).3163D	100g	265.40
	1ka	53.70	40 310-5	T <sub>m</sub> 172°C (DSC). Biodegradable polymer Poly(3-hydroxybutyric acid-co-3-hydroxyvaleric acid), natural origin	10q	32.40
14,200. Tm 55-65°	100mL	17.00	40,510-3	: [80181-31-3] [-COCH <sub>2</sub> CH(CH <sub>3</sub> )O-] <sub>k</sub> [-COCH <sub>2</sub> CH(C <sub>2</sub> H <sub>5</sub> )O-] <sub>y</sub> [α]b +4.5° (C=0.1, CHO <sub>3</sub> )	100g	207.80
32° d 1.090	250mL	. 34.00		PHV content 5 wt. %	.· •	
00 cps	•		€ .	Produced via a controlled fermentation process using microorganisms. Biodegradable	•	•
)70 d 4 000		17.00	40 211 2	polymer  Poly(3-hydroxybutyric acid-co-3-hydroxyvaleric acid), natural origin	10a	32.40
27° d 1.090	250g	, 34.00	40,311-0	[80181-31-3] [-COCH <sub>2</sub> CH(CH <sub>0</sub> )O-] <sub>k</sub> [-COCH <sub>2</sub> CH(C <sub>2</sub> H <sub>5</sub> )O-] <sub>y</sub> PHV content 8 wt. %	100g	207.80
0-8,000 cps	9			PHV content 8 wt. % Produced via a controlled fermentation process using microorganisms. Biodegradable		
d 1.140	7 100mL 250mL	17.70 32.10		polymer		
1 1 1	.3.	^	40,312-1	Poly(3-hydroxybutyric acid-co-3-hydroxyvaleric acid), natural origin	10g 100g	207.80
	.100mL .250mL	17.70 32.10		PHV content 12 wt. %	.,	
	•	: 17.70	1 22	Produced via a controlled fermentation process using microorganisms. Biodegradable polymer		14.50° 15
las 0/10 10/10	250mL	32.10		Poly(2-bydrovyethyl methacrylate) [25249-16-5] [-CH <sub>2</sub> C(CH <sub>2</sub> )(CO <sub>2</sub> CH <sub>2</sub> CH <sub>2</sub> OH)-] <sub>2</sub>	· 1g	13.20
lon 6/12 page 1240 1 6/9 page 1240				d 1.150 FT-IR-1(2),1194C-R&S 1(2),3167F	10g 25g	57.00 113.80
1-8]	250ml	20.30	18 213	Crystals. Average M <sub>v</sub> ca. 300,000 3 Poly(2-hydroxypropyl methacrylate) [25703-79-1]		
5 1.5340 d 1.100		20.00	9 197 ×	(-CH <sub>2</sub> C(CH <sub>3</sub> )[CO <sub>2</sub> CH <sub>2</sub> CH(OH)CH <sub>3</sub> ]-) <sub>n</sub> F1-IH 1(2),1190C Safety 2,267/A R&S 1(2),3165K	, <b>2</b> 59	134.20
IO page 1240				Crystals  Poly(4-hydroxystyrene), see Poly(4-vinylphenol)	رد اف	
10 page 1240 forms	100g	17.00	44 668	B Poly(indene-co-coumarone) [35343-70-5] d 1.140 Fp >230°F(110°C)	ikg	18.50
: ,	250g	34.00	W 10 *	Flake, Average Mn ca. 735, 10 wt. % coumarone	: JKg	41.40
190°C/2.16kg, DIN itio 20:80. Tg -65°, Tm			44.000	Flake. Average M <sub>n</sub> ca. 1,090. 10 wt. % coumarone	: 7kg 3ka	18.50 41.40
			19.195-	7 Poly(Isoborny) methacrylate)   64114-51-8   FT-IR 1(2),11948 R&S 1(2),316/E	10g	42.60
14-14-6] mp 33°	· 250g 1kg	21.30 58.80	*	Beads. Average M <sub>w</sub> ca. 554,000 (GPC). Tg 110°. Solubility parameter 8.1	1, 1, 1	
lity 2.0. Tm (DSC,	ing	30.00	6r, 18,145- ★		250g	46.30 80.70
a/t-adipic acid] dioi (110°C)	250mL 1L	20.50 56.50		Slab/chunk. Stabilized with 500 ppm 2,6-di-tert-butyl-4-methylphenol. Average M <sub>v</sub> ca. 420,000, M <sub>w</sub> ca. 500,000, M <sub>n</sub> ca. 200,000 (GPC/MALLS). Tg -76°. Tm 1.5°. Solubility parameter 7.7	9	
onality 2.1 1 <sub>2)5</sub> CH <sub>3</sub> ]-) <sub>n</sub> nB 1.4810	250	101.00	0118,146-	3 Polyisobutylene [9003-27-41 [-CH <sub>2</sub> C(CH <sub>2</sub> ) <sub>2</sub> -] <sub>0</sub>	100g	
ABLE LIQUID TOXIC Average M <sub>w</sub> ca.	<b>25</b> g	101.90	*	Slab/chunk. Stabilized with 500 ppm 2,6-di- <i>tert</i> -butyl-4-methylphenol. Average M <sub>v</sub> <i>ca.</i> 1,200,000, M <sub>w</sub> <i>ca.</i> 1,000,000, M <sub>n</sub> <i>ca.</i> 600,000 (GPC/MALLS)	250g	74.80
				CH <sub>4</sub> (CH <sub>2</sub> ) <sub>4</sub> CH <sub>2</sub>	_]	
; (CH <sub>2</sub> ) <sub>4</sub> CH <sub>2</sub> -				\\[\(\)\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	,UH <sub>3</sub>	
н <sub>2</sub> -с-сн <sub>2</sub> -				$(-s)^{\prime\prime}$ $(\frac{1}{1})^{\prime\prime}$	7	
∨п <sub>3</sub>	2		¥4.	44,570-3 44,668-8 19,195-7	- n	